

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

In re: Zytiga Litigation	Master Docket No. 19-12107 (KM)(ESK)
This Document Relates To: All Actions	STIPULATED DISCOVERY CONFIDENTIALITY ORDER

WHEREAS the Parties have, through counsel, stipulated to the entry of this Discovery Confidentiality Order to prevent dissemination or disclosure of confidential material, the Court hereby enters the following Discovery Confidentiality Order pursuant to Federal Rule of Civil Procedure 26(c) and Local Rule 5.3:

WHEREAS discovery in the above-captioned case (the “Action”) may involve the disclosure of certain documents, things, and information in the possession, custody, or control of Plaintiffs and Defendants or other persons that constitute or contain personal, sensitive proprietary information, such as trade secrets or other confidential research, development, technical, financial, business, competitive, or commercial information, within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure or other laws and regulations protecting such information;

WHEREAS such trade secret, confidential, or proprietary information must be protected in order to preserve the legitimate business interests of the parties or other persons;

WHEREAS, the Parties acknowledge that this Protective Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords only extends to the information or items that are entitled, under this Order and the applicable legal principles, to confidential treatment;

WHEREAS, the Parties further acknowledge that this Protective Order does not create entitlement to file Protected Information under seal, other than as set forth in this Order and Local Rule 5.3; and

WHEREAS the parties have, through counsel, stipulated to the entry of this Discovery Confidentiality Order for the purpose of advancing the progress of this Action and to protect the confidentiality of trade secret, confidential, personal or proprietary information that will be exchanged in the course of discovery in this Action; and

WHEREAS the parties have established good cause for entry of this appropriately tailored Discovery Confidentiality Order governing discovery in this Action;

Therefore, the following provisions of this Discovery Confidentiality Order shall control the disclosure, dissemination, and use of information in this case:

IT IS HEREBY ORDERED that:

1. Definitions

A. The term “Discovery Material” means any document or thing, and includes, without limitation, any writings, video, or audio tapes, computer-generated or recorded information in any form, materials, oral or written testimony, interrogatories, answers to interrogatories, requests for admission, responses to requests for admissions, document requests, responses to document requests, deposition testimony, deposition, hearing, or trial transcripts and exhibits, and other responses to requests for information or any tangible thing, produced by a party or non-party in this action.

B. The term “Protected Information” means information that has been designated in good faith by a party or non-party as containing or comprising “Confidential Information” or “Highly Confidential Information” pursuant to the provisions of this Discovery

Confidentiality Order, or that was designated “Highly Confidential OCEO Information” in underlying litigation concerning abiraterone acetate between Defendants in this Action and generic manufacturers who are non-parties to this Action (“underlying litigation”). Protected Information may include, without limitation, Discovery Material and other documents produced in this Action, during formal discovery or otherwise; information produced by non-parties which the Producing Party is under an obligation to maintain in confidence; and tangible things or objects that are designated as containing or comprising Protected Information. The information contained therein and all copies, abstracts, excerpts, analyses, or other writings that contain, reflect, reveal, suggest, or otherwise disclose such information shall also be deemed Protected Information. Information originally designated as Protected Information shall not retain that status after any ruling by the Court denying such status to it. Notwithstanding anything to the contrary herein, the description of Protected Information shall apply to all information so designated by the Producing Party absent an order of the Court, subsequent written agreement of the Producing Party providing otherwise, or if the document has since become public as a result of publication not involving a violation of this Order.

C. The term “Producing Party” means the persons or entities producing information and designating documents or information as Protected Information under this Discovery Confidentiality Order—including without limitation the parties to this Action, their representatives, agents, experts and consultants, all third parties providing discovery in this action, and all other interested persons with actual or constructive notice of this Protective Order.

D. The term “Receiving Party” shall mean the party or non-party subject to this Discovery Confidentiality Order to whom Protected Information is disclosed.

E. The term “Confidential Information” shall mean only those portions of confidential or sensitive, nonpublic product, business, commercial, or financial information or information of a proprietary technical nature that the Producing Party believes, in good faith, to be protected from public disclosure under Federal Rule of Civil Procedure 26(c), L. Civ. R. 5.3, or other applicable laws or regulations.

F. The term “Highly Confidential Information” relates to highly sensitive Confidential Information, the public disclosure of which the Producing Party believes, in good faith, will cause harm to the business, commercial, financial or personal interests of the Producing Party and/or a third party to whom a duty of confidentiality is owed. Examples of such information may include without limitation, nonpublic, highly sensitive information such as:

- i. Information relating to research and development for or production of products, including internal specifications;
- ii. Regulatory information, including information regarding Abbreviated New Drug Applications or New Drug Applications;
- iii. Business or research information;
- iv. Pending or abandoned patent, trademark and copyright applications, foreign or domestic, unless published or otherwise publicly available;
- v. Claims and reimbursement data;
- vi. Transactional data; or
- vii. Information protected by federal or state privacy laws or regulations.

G. The term “Highly Confidential-OCEO Information” relates only to information so designated in underlying litigation. The parties hereto agree to the maintenance of such designations in order to facilitate timely production of this category of information, but

further agree that any party may challenge the designation at any time if it believes, in good faith, that the designation is incorrect or improper. In such event, the challenging party shall utilize the dispute resolution mechanism set forth in paragraph 2.G, including, as appropriate, presenting the issue to the Court for resolution as set forth therein.

Designation of Protected Information

2. A Producing Party, whether a party to this action or a third party/non-party, may designate Protected Information as subject to this Discovery Confidentiality Order as follows:

A. With respect to documents or copies, by marking the document or the initial page and the page or pages on which any Protected Information appears with the legend “CONFIDENTIAL” (in the case of Confidential Information), or the legend “HIGHLY CONFIDENTIAL” (in the case of Highly Confidential Information). In the case of computer media, the Producing Party will note such designation in an accompanying cover letter and the designation shall be placed on the medium and its label and/or cover. To the extent practical, the designation shall be placed near the Bates number. In the case of a native file, the Producing Party will note such designation in an accompanying cover letter or slip sheet and the designation shall be included in the metadata and/or at the end of the file name and prior to the file extension.

B. When documents or things containing Protected Information are produced for inspection, the documents or things may be collectively designated as containing Protected Information for purposes of the inspection, by letter or otherwise, without marking each document or thing “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL,” and such documents or things will be treated as so designated under this Discovery Confidentiality Order. If any such documents or things are subsequently provided to the requesting party, they shall be marked in accordance with the preceding paragraph at that time.

C. A Producing Party may designate all or part of a deposition transcript as Protected Information (1) on the record at the deposition, or (2) by notifying the reporter and all counsel of record, in writing within thirty (30) days of receipt of the portion of the official transcript, the pages and line numbers containing such information by the Producing Party. All deposition testimony shall automatically be treated as containing Protected Information subject to this Discovery Confidentiality Order until thirty (30) days after the official transcript of such testimony is received by the party whose Protected Information is at issue.

D. Discovery Material, or any relevant portion of any letter, brief, memorandum, motion, affidavit, discovery response, discovery request, or other papers filed with the Court, may be designated as Protected Information by prominently marking such document or portion thereof with the legend “CONFIDENTIAL,” the legend “HIGHLY CONFIDENTIAL,” or, for documents so designated in the underlying litigation, the legend “HIGHLY CONFIDENTIAL-OCEO.”

E. If more than one designation has been applied to the same document, then the more restrictive designation controls.

F. An inadvertent failure to designate a document, thing, or testimony as Protected Information does not constitute forfeiture of a claim of confidentiality to that document, thing or testimony or to the same or related subject matter. In the event a Producing Party produced Protected Information without labeling or marking it as provided in this Discovery Confidentiality Order, the Producing Party may give written notice to the Receiving Party or parties after learning of the inadvertent production, that the document, thing or other discovery information, response or testimony contains or comprises Protected Information and should be treated as such in accordance with the provisions of this Discovery Confidentiality Order. The Producing Party will

also promptly provide properly marked copies of the information. Upon receipt of such notice and properly marked information, the Receiving Party or parties shall either return said unmarked or incorrectly marked information to the extent reasonably practicable and shall not retain copies thereof, or certify in writing that the Receiving Party has destroyed the unmarked or incorrectly marked information to the extent reasonably practicable, and shall undertake reasonable efforts to correct any disclosure of such information contrary to the redesignation. Prior to receipt of such notice, disclosure of such documents, things, information, responses, and testimony to persons not authorized to receive Protected Information shall not be deemed a violation of this Discovery Confidentiality Order. This paragraph shall be interpreted to provide the maximum confidentiality protection allowed under applicable law.

G. Any Receiving Party may at any time request that the Producing Party or a third-party who originally designated the document in prior proceeding (a “Designating Third-Party”) withdraw a designation with respect to any document, object, or information. Any such request shall be in writing, and shall particularly identify the Protected Information that the Receiving Party contends is not properly designated as Protected Information, along with the reasons supporting that contention. If the Producing Party or Designating Third-Party does not agree to withdraw the designation, the Producing Party and/or the Designating Third-Party shall then meet and confer with the Receiving Party to attempt to resolve the dispute without involvement of the Court. If the parties cannot resolve the dispute, then the Receiving Party may file an application to redesignate the document(s) or information in question no less than seven (7) days after the Receiving Party's initial request to withdraw the designation, unless exigent circumstances warrant a shorter time period for resolving the dispute, and shall serve the application on any Designating Third-Party. With respect to any such application, the Producing

Party or the Designating Third-Party shall bear the burden of establishing that the document(s) or information is properly designated under this Discovery Confidentiality Order. Until the application is resolved by agreement of the parties or by the Court, information designated as Protected Information shall retain its designation.

H. Any information previously designated in the underlying litigation may be produced in this Action bearing the same confidentiality designation assigned to it in the underlying litigation. No additional markings need to be put on those documents prior to production in this Action, and the information contained in such documents shall be treated under the initial designation as spelled out in this Order.

Disclosure of Protected Information

3. **Disclosure of Confidential Information.** The Receiving Party may make Confidential Information of the Producing Party, and any document, analysis, report, or other item containing Confidential Information of the Producing Party, available and accessible only to the following individuals:

A. Attorneys, employees, or staff employed by any of the law firms of record representing a party in this Action.

B. A person identified in the Protected Information as an author; source; addressee; recipient of the material or who already has a copy of it; any person who according to the face of the document has knowledge of the document or the Protected Information therein; any deponent, at their deposition, who counsel has a good-faith basis to believe reviewed or had personal knowledge of the specific subject matter of the Discovery Material prior to its production in this Action, and such a belief is confirmed by first laying a foundation as to that personal knowledge consistent with Federal Rule of Evidence 602; any employee, director, or

agent of the Producing Party; or any witness designated to testify as a Rule 30(b)(6) witness on behalf of the Producing Party.

C. Independent consultants or experts (and their staff) retained by an attorney for a party or by a party either as consultants or expert witnesses for the purposes of this litigation, provided such person has first executed the Declaration of Compliance in the form annexed as an Exhibit hereto.

D. Vendor(s) retained by or for a party to assist in preparing for pretrial discovery, trial, and/or hearings including, but not limited to, outside copying and computer services necessary for document handling, trial consultants, translators, and other litigation support personnel (*e.g.*, graphic designers and animators.)

E. The Court, including any appellate court, Court personnel, court reporters, mediators or arbitrators, interpreters, and videographers, and their staff, engaged in association with this Action.

F. The parties.

4. **Disclosure of Highly Confidential Information.** The Receiving Party may make Highly Confidential Information of the Producing Party, and any document, analysis, report, or other item containing Highly Confidential Information of the Producing Party, available and accessible only to those persons listed in paragraphs 3(A) – (E) and additional persons as set forth in subparagraphs (A)-(F) below.

A. A total of no more than four individual representatives (along with their secretarial and/or paralegal staff) for each party.

B. For purposes of this paragraph, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development LLC, and Johnson & Johnson (collectively, “Janssen”) shall be considered a single corporate party.

C. For purposes of this paragraph, Defendant BTG International Limited shall be able to have four representatives designated specifically for the antitrust cases and four representatives designated specifically for the qui tam case.

D. For purposes of this paragraph, Janssen shall be able to have four representatives designated specifically for the antitrust cases and four representatives designated specifically for the qui tam.

E. The designated party representatives are prohibited from using such Highly Confidential Information or information derived therefrom for any purpose other than to carry out their duties related to this litigation. Designated party representatives are prohibited from giving, showing, making available, discussing, or otherwise communicating Highly Confidential Information in any manner, either directly or indirectly, to any person or entity not authorized to receive such information under the terms of this Order.

F. Should a designated party representative transition off of duties related to this litigation, a party may replace that prior designated party representative with a newly designated representative.

5. **Disclosure of Highly Confidential-OCEO Information.** The Receiving Party may make Highly Confidential-OCEO Information of the Producing Party, and any document, analysis, report, or other item containing Highly Confidential-OCEO Information of the Producing Party, available and accessible only to those persons listed in paragraphs 3(A) – (E) and subject to any conditions thereof. Defendants will not challenge the adequacy of the named plaintiff

representatives in this litigation for class certification purposes based upon the plaintiffs' inability to review the documents produced by Defendants as 'Highly Confidential-OCEO' or any documents that quote documents produced by Defendants as 'Highly Confidential-OCEO' under this paragraph.

6. **Data Security and Protection.** Protected Information must be stored and maintained by a Receiving Party at a location and in a secure manner that reasonably ensures that access is limited to the persons authorized under this Order, as such material may be proprietary, commercially sensitive or contain personally identifying information. Each person who has access to Protected Information shall (i) take all necessary and prudent measures to preserve the security of the Protected Information and prevent the unauthorized access to or inadvertent disclosure of such material; and (ii) shall physically store, maintain, and transmit Protected Information solely within the United States.

7. **Breach of Data Security and Protection.** The following requirements apply in the event that unauthorized access to or acquisition of Protected Information (other than a party's own Protected Information) is reasonably likely to have occurred (a "Breach"):

A. Persons with knowledge of the Breach shall take immediate necessary and prudent remedial measures, including any measures in compliance with state and regulatory requirements, to prevent reoccurrence of a Breach.

B. Persons with knowledge of the Breach shall promptly inform the Producing Party of all facts relating to the Breach, including identification of Protected Information subject to the Breach, and remedial measures taken in response to the Breach.

Use and Control of Protected Information

8. The restrictions of this Discovery Confidentiality Order continue to apply to any person who is, or was at any time, an authorized recipient of Protected Information under Paragraphs 3, 4, or 5.

9. All information designated as Protected Information pursuant to this Discovery Confidentiality Order and disclosed in this Action shall be used by a recipient thereof solely for the purposes of this litigation and not for any business, commercial, regulatory, competitive, patent prosecution purposes, or other purposes.

10. If a person or entity serves a party in this action with a request, subpoena, or order (“demand”) for disclosure of Protected Information of a Producing Party, the party receiving the demand, if not prohibited under applicable law and within 48 hours of receipt, shall deliver a copy of the demand to the Producing Party’s counsel. The party shall not disclose any Protected Information prior to the date specified for disclosure except as required by law or a Court. In its sole discretion and at its own cost, the Producing Party may oppose or seek to limit the demand in any legal manner. If the Producing Party does not, by the date specified for disclosure, advise the party who received the demand that it intends to seek prompt judicial relief, the party receiving the demand shall produce it to the requesting party.

11. Nothing herein shall prevent (a) any party from disclosing and using its own Protected Information in any manner that it considers appropriate; (b) counsel for either party from showing or using Protected Information obtained from the opposing party during examination (at deposition, trial, or other proceeding in this Action) of any current or former officer, employee, agent, Rule 30(b)(6) designee, or retained expert of the party who designated the information; or (c) the disclosure of Protected Information of a Producing Party to any person who either authored

the Protected Information in whole or in part, or who received the Protected Information while he or she was an officer, employee, agent, or otherwise affiliated with the Producing Party.

12. In the event that any question is asked at a deposition that calls for the disclosure of Protected Information, the witness shall nevertheless answer such question subject to any legal privilege or protection that may prevent the witness from answering. Any person present for the deposition who is not authorized to receive Protected Information, as appropriate, may be asked to leave the room and upon such request shall leave the deposition room until such time as the Protected Information is no longer being disclosed.

Miscellaneous

13. This Discovery Confidentiality Order shall remain in force and effect indefinitely until modified, superseded, or terminated by order of this Court. The entry of this Order does not preclude any party in this action from seeking further order of this Court, including modification of this Order, or from objecting to discovery that the party believes to be improper.

14. This Order is binding on all current and future parties in this action (including their respective corporate parents, subsidiaries, affiliates, successors, and attorneys and all other representatives or agents), their counsel, and all signatories to Exhibit 1, the Declaration of Compliance with the Discovery Confidentiality Order (deemed to be part of this Order), and all other persons or entities authorized under this Order or any other Order of this Court to receive or view Protected Information.

15. Nothing herein shall be construed as an admission or concession by a Producing Party that any Protected Information constitutes relevant, material, or admissible evidence in this matter.

16. Any party seeking to file papers with the Court containing Protected Information shall file them temporarily under seal and subsequently file a joint motion to seal, or otherwise restrict public access to, those materials pursuant to Local Civil Rules 5.3(c), as amended March 24, 2021. All such documents so filed shall be released from confidential treatment by the Court only upon further order of the Court or agreement of the parties.

A. The burden of proving to the Court that such material designated as Protected Information should be sealed under Local Civil Rule 5.3 shall at all times remain with the party that initially produced the material and designated it as Protected Information, and

B. If the party filing the material is not the Producing Party, the filing party nonetheless is obligated to make a reasonable effort when filing material designated as Protected Information to meet the provisions of Local Civil Rule 5.3 to protect the Producing Party's materials.

C. In addition to the filing of a motion to seal, the parties, including designating non-parties, agree to comply with the procedures for filing public redacted versions as set forth in Local Civil Rule 5.3(C)(4).

17. Nothing in this Discovery Confidentiality Order shall bar or otherwise restrict any attorney for the parties from rendering advice to his or her client with respect to this litigation. In the course of doing so, said attorney may generally refer to or rely upon his or her examination of Protected Information but shall not disclose the specific contents of such information to persons not authorized to receive such information pursuant to this Discovery Confidentiality Order, except by written agreement with opposing counsel of record.

18. Each Receiving Party shall, within ninety (90) days of final termination of this Action (including all appeals), either return to the Producing Party or destroy all of the Producing Party's Protected Information in the Receiving Party's possession. Notwithstanding the foregoing: As to those materials that contain, reflect, incorporate, attach, or reference attorney work product, counsel of record for the Parties shall be entitled, without violating this Order, to retain such work product in their files, so long as the terms of this Order will continue to govern any such retained materials. In addition, counsel of record for the Parties shall be entitled, without violating this Order, to retain pleadings, affidavits, motions, briefs, expert reports (and exhibits thereto), correspondence (including internal correspondence and e-mail), any other papers filed with the Court (including exhibits), deposition transcripts, and the trial record (including exhibits) even if such materials contain or describe Confidential Material or Highly Confidential Material, so long as this Order will continue to govern any such retained materials. The Receiving Party's commercially reasonable efforts shall not require the return or destruction of materials that (a) are stored on backup storage media made in accordance with regular data backup procedures; (b) are located in the email archive system or archived electronic files of departed employees; or (c) are subject to legal hold obligations, provided, however, that (i) any such material shall be treated in accordance with this Order; (ii) to the extent that any material is accessed from backup storage media, information protected by data privacy obligations shall be destroyed or returned; (iii) to the extent that any material is accessed from an email archive system or archived electronic files of departed employees, information protected by data privacy obligations shall be destroyed or returned; and (iv) legal hold obligations shall be periodically reviewed for necessity and proportionality and information protected by data privacy obligations shall not be retained in perpetuity. Nothing in this Paragraph shall obligate any Party to destroy its own Confidential

Information at the close of this Action or at any other time. This Order shall continue to apply to any such materials retained by counsel.

19. **[Defendants' Proposal]** The parties have agreed that they do not intend to disclose Privileged Information in this Action. Pursuant to FRE 502(d) and 28 U.S. Code § 1738, any disclosure of Privileged Information ("Disclosed Privileged Information"), inadvertent or otherwise, shall not constitute in this or any other action a waiver or forfeiture of any privilege otherwise attaching to the Disclosed Privileged Information and its subject matter. Disclosed Privileged Information shall receive the maximum protection afforded by FRE 502(d). This Order shall be enforceable and granted full faith and credit in all other state and federal proceedings. A party that produces documents or information subject to the attorney-client privilege or work-product immunity may request return of such documents or information after the Producing Party learns of its production. After receipt of such a request, the Receiving Party shall promptly return, sequester, or destroy the specified information and any copies of and notes pertaining to such information as soon as possible, and in any event within seven (7) days of receipt of such a request. For purposes of this section, it shall be irrelevant which party initially discovers the produced information, documents, or tangible items that are otherwise properly subject to a claim of attorney-client privilege, work product immunity, or any other protection from discovery. Any subsequent conflict of law analysis shall apply the law most protective of privilege and work product. For avoidance of doubt, nothing in this provision shall prevent any party from challenging another party's designation of information as privileged or subject to the attorney work product doctrine.

19. **[Plaintiffs' Proposal]** The parties have agreed that they do not intend to disclose Privileged Information in this Action. Pursuant to FRE 502(d) and 28 U.S. Code § 1738, any

disclosure of Privileged Information (“Disclosed Privileged Information”), inadvertent or otherwise, shall not constitute in this or any other action a waiver or forfeiture of any privilege otherwise attaching to the Disclosed Privileged Information and its subject matter, unless deemed by the Court to be a waiver or forfeiture. This Order shall be enforceable and granted full faith and credit in all other state and federal proceedings. A party that produces documents or information subject to the attorney-client privilege or work-product immunity may request return of such documents or information after the Producing Party learns of its production. After receipt of such a request, the Receiving Party shall promptly return, sequester, or destroy the specified information and any copies of and notes pertaining to such information as soon as possible, and in any event within seven (7) days of receipt of such a request. For purposes of this section, it shall be irrelevant which party initially discovers the produced information, documents, or tangible items that are otherwise properly subject to a claim of attorney-client privilege, work product immunity, or any other protection from discovery. Any subsequent conflict of law analysis shall apply the law most protective of privilege and work product. For avoidance of doubt, nothing in this provision shall prevent any party from challenging another party’s designation of information as privileged or subject to the attorney work product doctrine.

It is hereby ORDERED:

Dated: June __, 2021

Hon. Edward S. Kiel, U.S.M.J.
United States Magistrate Judge

EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

In re: Zytiga Litigation	Master Docket No. 19-12107 (KM)(ESI)
This Document Relates To: All Actions	

DECLARATION OF COMPLIANCE

I, _____, state the following under penalty of perjury:

I have read the attached Stipulated Discovery Confidentiality Order entered in the above-captioned case and understand its terms. I will hold in confidence and not disclose to anyone not qualified under the Stipulated Discovery Confidentiality Order any Protected Information or any words, summaries, abstracts or indices of such information disclosed to me. In particular, I further understand that I may use information designated as Confidential, Highly Confidential, or Highly Confidential-OCEO pursuant to the Discovery Confidentiality Order only for the purposes of this litigation and not for any business, commercial, regulatory, competitive, patent prosecution or other purposes. No later than the final conclusion of this case, upon request, I will return or destroy all Confidential, Highly Confidential, or Highly Confidential-OCEO Information and summaries, abstracts and indices thereof which come into my possession, and documents or things which I have prepared relating thereto, to counsel for the party for whom I was employed or retained. By signing this declaration, I agree to be bound by all the terms of the Stipulated Discovery Confidentiality Order entered in this case, and I submit to the jurisdiction of United States District Court for the District of New Jersey for purposes of the enforcement of that Order.

Dated: _____

Signature: _____

